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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,227	07/02/2003	Jeffrey Grossman	31132.164	1226
46333	7590	01/10/2008	EXAMINER	
HAYNES AND BOONE, LLP 901 Main Street Suite 3100 Dallas, TX 75202			RYCKMAN, MELISSA K	
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/604,227	GROSSMAN, JEFFREY	
	<b>Examiner</b>	<b>Art Unit</b>	
	Melissa Ryckman	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 3/23/07.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,4-26 and 28-30 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,4-26 and 28-30 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

This office action is in response to claims and arguments filed 6/29/07.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-26 and 28-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Kitaevich et al. (U.S. Patent No. 5,598,269).

Claims 1, 13, 22 and 28:

Kitaevich teaches an insertion device trajectory system for use with an insertion device in treating a patient, comprising: an energy source (106) for producing an energy path in a direction away from the patient; an indication surface for indicating a trajectory of the energy path (surface near 106, where 108 strikes, col. 7, ll. 1), thereby indicating any trajectory correction required for the insertion device; and a reflecting element (102) spaced from the energy source and configured to reflect the energy path towards the indication surface (Fig. 7). Kitaevich does not specify the energy source being attached to the insertion device, however using rearrangement of parts [In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950); In re Kuhle, 526 F.2d 553, 188 USPQ7 (CCPA 1975)] The examiner rearranges element 102 and element 106 as these tools are used for the purpose of alignment (col. 7, ll. 5 Kitaevich), Kitaevich then has a mechanism by which

the energy source can be attached to the insertion device (106 is inherently attaches to element 100 after rearrangement of parts, sensor, col. 7, ll. 6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kitaevich by rearranging 106 and 102 as these are tools used for aligning the device that is inserted into the body, it is simply a matter of design choice to put the energy source 106 on the insertion tool because it performs equally as well with the energy source directed at the insertion tool, as the purpose is for alignment of the insertion tool.

Claim 18:

Kitaevich teaches a method of aligning a medical instrument used in treating a patient, the method comprising: generating an energy path (104) from an energy source located on the medical instrument, the energy path directed away from the patient (after rearrangement of parts the energy path is directed away from the patient, parts [In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950);In re Kuhle, 526 F.2d 553, 188 USPQ7 (CCPA 1975)] The examiner rearranges element 102 and element 106 as these tools are used for the purpose of alignment (col. 7, ll. 5 Kitaevich), Kitaevich then has a mechanism by which the energy source can be attached to the insertion device (106 is inherently attaches to element 100 after rearrangement of parts, sensor, col. 7, ll. 6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kitaevich by rearranging 106 and 102 as these are tools used for aligning the device that is inserted into the body. ); and reflecting the energy path so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the medical instrument (col. 7, ll. 5).

Claims 4,16 and 29:

Kitaevich teaches the energy source comprises a light source (106).

Claim 5:

Kitaevich teaches the light source being a laser, however it would have been obvious to one of ordinary skill in the art to use a LED as it is a well known source of light in the field and would work equally as well as the laser light source.

Claim 6:

Kitaevich teaches the energy path (Fig. 7, 104, 108) comprises a directed light, and wherein the attachment mechanism is adapted to direct the light towards a reflecting element (102).

Claim 7:

Kitaevich teaches the indication surface (surface near 106, where 108 strikes, col. 7, II. 1, sensor, col. 7, II. 6) is positioned so that the light directed towards the reflecting element (102) is visibly identifiable on the indication surface (Fig. 7).

Claim 8:

Kitaevich teaches the energy source is permanently secured to the insertion device by the attachment mechanism (after rearrangement of parts as discussed in claim 1 above, 106 would inherently be part of element 100).

Claim 9:

Kitaevich teaches a workpiece (distal end of 100) is attached to a distal end of the insertion device (100), and wherein the attachment mechanism is configured so that

the energy path from the energy source is coaxial with the workpiece (after rearrangement of parts the energy path 104 is coaxial with the distal end of 100).

Claims 10,17,23,24:

Kitaevich teaches the workpiece is a percutaneous needle (distal end of 100 is a biopsy tool, col. 7, ll. 14).

Claim 11:

Kitaevich teaches a visual indicator for indicating a trajectory of the energy path (alarm, col. 7, ll. 9).

Claims 12 and 15:

Kitaevich teaches a reflecting element (102), however Kitaevich does not specify a radiolucent material, however it is well known in the art to us a reflective radiolucent material as a reflecting surface, as it would perform equally as well as a mirror.

Claim 14:

Kitaevich teaches the surface (sensor, col. 7, ll. 6) is located adjacent the energy source (106).

Claim 19:

Kitaevich teaches the reflected energy path (104) is directed towards an indication surface (sensor, col. 7, ll. 6) located on the energy source.

Claim 20:

Kitaevich teaches operating the medical instrument through a driver (medical instrument is distal end of element 100, and the driver is element 100).

Claim 21:

Kitaevich teaches the medical instrument comprises a needle (distal portion of 100, biopsy tool, col. 7, ll. 14).

Claim 25:

Kitaevich teaches a longitudinal axis extending at least partially between the working end and the proximal end (100, inherently has a longitudinal axis).

Claim 26:

Kitaevich teaches the energy source is adapted to produce an energy path substantially parallel to the longitudinal axis (Fig. 7).

Claim 30:

Kitaevich teaches the energy source (106) is adapted to selectively engage the proximal end of the instrument (Fig. 7).

### ***Response to Arguments***

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR



(JACKIE) TAN-UYEN HO  
SUPERVISORY PATENT EXAMINER